

Class of substance	Substance	Purpose	Products	Amount
	Papain .....	To soften tissue .....	Raw poultry muscle tissue of hen, cock, mature turkey, mature duck, mature goose, and mature guinea, and raw meat cuts.	Solutions consisting of water and approved proteolytic enzyme applied or injected into raw meat or poultry tissue shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Potassium chloride	.....do .....	.....do .....	Not more than 3 percent of a 2.0 molar solution.
	Potassium, magnesium or calcium chloride.	.....do .....	.....do .....	A solution of approved inorganic chlorides injected into or applied to raw meats or poultry cuts shall not result in a gain of more than 3 percent above the weight of the untreated product.

<sup>1</sup> [Reserved]

<sup>2</sup> Information as to the specific products for which use of this additive is approved may be obtained upon inquiry addressed to the Labeling and Additives Policy Division, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

<sup>3</sup> Provided, that its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the desired technical effect as determined in specific cases prior to label approval under §§ 317.4 or 381.32.

<sup>4</sup> Special labeling requirements are prescribed in 381.120 for raw poultry chilled in a medium with more than 70 lbs. of salt to 10,000 gals. of water.

[64 FR 72175, Dec. 23, 1999, as amended at 65 FR 3123, Jan. 20, 2000; 65 FR 34391, May 30, 2000]

#### § 424.22 Certain other permitted uses.

(a) Under appropriate declaration as required in parts 316 and 317 of this chapter, the following substances may be added to meat:

(1) *General.* Common salt, approved sugars (sucrose, cane or beet sugar), maple sugar, dextrose, invert sugar, honey, corn syrup solids (corn syrup, glucose syrup and fructose), wood smoke, vinegar, flavorings, spices, sodium nitrate, sodium nitrite, potassium nitrate, potassium nitrite, and other food and color additives specified in the chart in paragraph (c) of this section may be added to meat under conditions, if any, specified in this part or in part 317 of this chapter.

(2) *Artificial flavorings.* Other harmless artificial flavorings may be added to meat, with the approval of the Administrator in specific cases.

(3) *Coloring matter and dyes.* Coloring matter and dyes, other than those specified in a regulation permitting that use in this chapter or in 21 CFR Chapter I, Subchapter A and Subchapter B, may be applied to meat mixed with rendered fat, applied to natural and artificial casings, and applied to such casings enclosing products, if approved by the Administrator

in specific cases. When any coloring matter or dye is applied to casings, there shall be no penetration of coloring into the product.

(b) *Use of nitrite and sodium ascorbate or sodium erythorbate (isoascorbate) in bacon—*(1) *Pumped bacon.* With respect to bacon injected with curing ingredients and massaged bacon, sodium nitrite shall be used at 120 parts per million (ppm) ingoing or an equivalent amount of potassium nitrite shall be used (148 ppm ingoing); and 550 ppm of sodium ascorbate or sodium erythorbate (isoascorbate) shall be used. Sodium ascorbate or sodium erythorbate have a molecular weight of approximately 198. Hydrated forms of these substances shall be adjusted to attain the equivalent of 550 ppm of sodium ascorbate or sodium erythorbate.

(i) The Department shall collect samples of pumped bacon from producing plants and analyze them for the level of nitrosamines by the Thermal Energy Analyzer (TEA). In the event that a TEA analysis indicates that a confirmable level of nitrosamines might be present, additional samples shall be collected and analyzed by gas chromatography. Presumptive positive results must be confirmed by mass spectrometry before being considered positive. If

during the interval required for the Department to analyze the confirmatory samples by gas chromatography and mass spectrometry, changes are made in processing procedures which are expected to result in no confirmable levels of nitrosamines in pumped bacon produced by these new procedures, an establishment may submit samples to USDA for analysis upon prior notification and arrangements with USDA. If, however, an establishment furnishes USDA with laboratory results from testing five consecutive lots of pumped bacon produced under the new procedures and the testing is performed by the USDA methodology and procedures, those results will be utilized in making the determination concerning the product produced under the new procedures. Should the results of these tests reveal that confirmable levels of nitrosamines are not indicated in any of the five consecutive lots, the confirmation analysis by USDA shall be terminated and the establishment shall revert to normal monitoring status. In the event the test results continue to indicate nitrosamines, however, USDA shall proceed in its confirmation analysis on the original samples taken for confirmation. If any one of the original samples collected by USDA for confirmation is found to contain confirmable levels of nitrosamines, all pumped bacon in the producing establishment and all future production will be retained. The Department shall sample and analyze such retained pumped bacon for nitrosamines on a lot by lot basis. A production lot shall be that pumped bacon produced by the establishment in any single shift. Samples from any lot of pumped bacon under retention found to contain nitrosamines at a confirmable level shall cause the lot of pumped bacon to be disposed of in a manner to ensure it will not form nitrosamines when cooked. Such disposal may include incorporation of the uncooked pumped bacon as an ingredient of another meat provided it is processed for eating without further preparation in a manner to preclude the formation of nitrosamines. Bacon subsequently produced shall not be retained because of nitrosamines if the operator of the establishment makes adjustments in the processing of the

product and laboratory results obtained by TEA analysis of samples from five consecutive normal sized lots of pumped bacon indicates that the product being produced contains no confirmable levels of nitrosamines. These tests from five consecutive normal sized lots of pumped bacon shall be conducted by the Department. However, if the establishment furnishes the Department with the results of tests conducted under the methodology and procedures used by the Department, such test results will be utilized in making the determination concerning the nitrosamine content of the product. All tests of pumped bacon for nitrosamines under this paragraph (b)(1)(i) shall be made on pumped bacon cooked at 340 degrees F. for 3 minutes on each side. In order to determine that no confirmable levels of nitrosamines are present in a sample tested, the testing must be performed by methodology and procedures that would detect the presence of any nitrosamines at 10 ppb.

(ii) Notwithstanding the provisions of paragraph (b)(1)(i) of this section, sodium nitrite may be used at:

(A) 100 ppm ingoing (potassium nitrite at 123 ppm ingoing); and 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate) shall be used; or

(B) A predetermined level between 40 and 80 ppm (potassium nitrite at a level between 49 and 99 ppm); 550 ppm sodium ascorbate or sodium erythorbate (isoascorbate); and additional sucrose or other similar fermentable carbohydrate at a minimum of 0.7 percent and an inoculum of lactic acid producing bacteria such as *Pediococcus acetolactii* or other bacteria demonstrated to be equally effective in preventing the production of botulinum toxin at a level sufficient for the purpose of preventing the production of botulinum toxin.

(C) The Department shall collect samples of bacon from establishments producing under paragraph (b)(1)(ii) of this section and analyze them for the level of nitrosamines. Samples shall be randomly selected throughout the production of a lot. The actual sampling plans and methods of analysis that are used will result in approximately the

same likelihood as under paragraph (b)(1)(i) of this section of having a presumptive positive result when the true mean level of nitrosamines in a production lot is 10 ppb. In the event of a presumptive positive result, the establishment shall become subject to the provisions of paragraph (b)(1)(i) of this section.

(2) *Immersion cured bacon.* Immersion cured bacon may be placed in a brine solution containing salt, nitrite and flavoring material or in a container with salt, nitrite and flavoring material. Sodium nitrite shall not exceed 120 ppm ingoing or an equivalent amount of potassium nitrite (148 ppm ingoing) based on the actual or estimated skin-free green weight of the bacon bellies.

(3) *Bacon made with dry curing materials.* With respect to bacon made with dry curing materials, the product shall be cured by applying a premeasured amount of cure mixture to the bacon belly surfaces, completely covering the surfaces. Sodium nitrite shall not exceed 200 ppm ingoing or an equivalent amount of potassium nitrite (246 ppm ingoing) in dry cured bacon based on the actual or estimated skin-free green weight of the bacon belly.

(c) Irradiation of meat food and poultry products.

(1) *General requirements.* Meat food and poultry products may be treated to reduce foodborne pathogens and to extend product shelf-life by the use of sources of ionizing radiation as identified in 21 CFR 179.26(a). Official establishments must irradiate meat food and poultry products in accordance with 21 CFR 179.26(b), the Hazard Analysis and Critical Control Point (HACCP) system requirements in part 417 of this chapter, and the provisions of this section.

(2) *Dosimetry.* Official establishments that irradiate meat food and poultry products must have the following procedures in place:

(i) Laboratory operation procedures for determining the absorbed dose value from the dosimeter.

(ii) Calibration criteria for verifying the accuracy and consistency of any means of measurement (*e.g.*, time clocks and weight scales).

(iii) Calibration and accountability criteria for verifying the traceability and accuracy of dosimeters for the intended purpose, and the verification of calibration at least every 12 months. To confirm traceability, establishments must relate, through documentation, the end point measurement of a dosimeter to recognized standards.

(iv) Procedures for ensuring that the product unit is dose mapped to identify the regions of minimum and maximum absorbed dose and such regions are consistent from one product unit to another of like product.

(v) Procedures for accounting for the total absorbed dose received by the product unit (*e.g.*, partial applications of the absorbed dose within one production lot).

(vi) Procedures for verifying routine dosimetry, *i.e.*, assuring each production lot receives the total absorbed dose. Establishments may either position one dosimeter at the regions of minimum and maximum absorbed dose (or at one region verified to represent such) on at least the first, middle, and last product unit in each production lot or use statistically based validation and dose mapping to determine the number and placement of dosimeters in each production lot.

(vii) Procedures for verifying the relationship of absorbed dose as measured by the dosimeter to time exposure of the product unit to the radiation source.

(viii) Procedures for verifying the integrity of the radiation source and processing procedure. Aside from expected and verified radiation source activity decay for radionuclide sources, the radiation source or processing procedure must not be altered, modified, replenished, or adjusted without repeating dose mapping of product units to redefine the regions of minimum and maximum absorbed dose.

(3) *Documentation.* Official establishments that irradiate meat food or poultry products must have the following documentation on premises, available to FSIS:

(i) Documentation that the irradiation facility is licensed or possesses gamma radiation sources registered with the Nuclear Regulatory Commission (NRC) or the appropriate State

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government acting under authority granted by the NRC.

(ii) Documentation that the machine radiation source irradiation facility is registered with the appropriate State government, if applicable.

(iii) Documentation that a worker safety program addressing OSHA regulations (29 CFR chapter XVII) is in place.

(iv) Citations or other documents that relate to incidences in which the establishment was found not to comply with Federal or State agency requirements for irradiation facilities.

(v) A certification by the operator that the irradiation facility personnel will only operate under supervision of a person who has successfully completed a course of instruction for operators of food irradiation facilities.

(vi) A certification by the operator that the key irradiation personnel, who monitor or control daily operations, have been trained in food technology, irradiation processing, and radiation health and safety.

(vii) Guarantees from the suppliers of all food-contact packaging materials that may be subject to irradiation that those materials comply with the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(4) *Labeling.* (i) The labels on packages of meat food and poultry products irradiated in their entirety, in conformance with this section and with 21 CFR 179.26(a) and (b), must bear the logo shown at the end of this paragraph (c)(4)(i). Unless the word “Irradiated” is part of the product name, labels also must bear a statement such as “Treated with radiation” or “Treated by irradiation.” The logo must be placed in conjunction with the required statement, if the statement is used. The statement is not required to be more prominent than the declaration of ingredients required under § 317.2(c)(2). Any label bearing the logo or any wording of explanation with respect to this logo must be approved as required by Section 317.4. of this chapter or subparts M and N of part 381.



(ii) For meat food or poultry products that have been irradiated in their entirety, but that are not sold in packages, the required logo must be displayed to the purchaser with either the labeling of the bulk container plainly in view or a counter sign, card, or other appropriate device bearing the information that the product has been treated with radiation. In either case, the information must be prominently and conspicuously displayed to purchasers. Unless the word “Irradiated” is part of the product name, the labeling counter sign, card, or other device also must bear a statement such as “Treated with radiation” or “Treated by irradiation.” The logo must be placed in conjunction with the required statement, if the statement is used.

(iii) The inclusion of an irradiated meat food or poultry product ingredient in any multi-ingredient meat food or poultry product must be reflected in the ingredient statement on the finished product labeling.

(iv) Optional labeling statements about the purpose for radiation processing may be included on the product label in addition to the stated requirements elsewhere in this section, provided that such statements are not false or misleading. Statements that there has been a specific reduction in microbial pathogens must be substantiated by processing documentation.

[64 FR 72175, Dec. 23, 1999, as amended at 64 FR 72165, Dec. 23, 1999; 65 FR 34391, May 30, 2000]

### § 424.23 Prohibited uses.

(a) *Substances that conceal damage or inferiority or make products appear better or of greater value.* No substance may be used in or on any meat if it conceals damage or inferiority or makes the